IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	
Smith	:	Examiner: Zachariah Lucas
Serial No. 10/568,176	:	
Filed: November 30, 2006	:	Art Unit: 1648
For: METHODS OF TREATING VIRAL INFECTIONS	:	

Date: September 11, 2009

Petition for Suspension of Prosecution (37 CFR 1.103(a))

Assistant Commissioner for Patents
MAIL STOP After-Final
P.O. BOX 1450
ALEXANDRIA, VA 22131-1450

Dear Sir:

Applicant hereby petitions the commission to suspend prosecution in the above entitled application for an additional period of 6 months.

C.F.R. 1.103(a) provides for the suspension of prosecution in an application for good and sufficient cause.

In the instant application, applicant has filed a response to the outstanding Final rejection issued October 22, 2008. In addition, applicant has filed a Request for Continuing Examination.

In the most recent Office action, the Examiner has suggested that evidence demonstrating unexpected results over the prior art might be appropriate and relevant to the question of obviousness. Applicant has completed the study of the feasibility and costs relating to possible animal studies which would demonstrate the results alleged in the application. Such animal studies do take time and applicant would like to put such evidence before the Examiner prior to further action in the application.

Applicant has developed a plan as well as provided for the studies to be performed in order to complete the animal studies originally discussed and which are deemed likely to satisfy the patent examiners request for a showing as set forth in the most recent Office action. The following is an outline of the proposed studies:

Experimental design:

36 rats will be divided into 3 groups with 12 rats in each group and 4 rats in each time point.

Group 1: Rats will be administered by gavages of ribavirin at 14 mg/kg. The rats will be sacrificed 2, 6, 24 hours after administration with 4 rats at each time point.

Group 2: Rats will be administered ribavirin over 24 h in 20 ml of drinking water at 14 mg/kg. After 24 h, rats will be given back normal water and then will be sacrificed 2, 6, 24 hours after that with 4 rats at each time point. (For example, if rats are given 20 ml of drinking water containing ribavirin from Day 1 8 am, then ribavirin containing water will be taken away on 8 am of Day 2 and rats will be sacrificed on 10 am, 2 pm of Day 2 and 8 am of Day 3)

Group 3: Rats will be administered of ribavirin over 24 h in 20 ml of drinking water at 7 mg/kg.

Blood samples will be collected from portal vein and femoral vein before rats are sacrificed. Liver and skeletal muscle will be collected after sacrifice of rats.

Sample analysis:
Ribavirin concentration in plasma, red blood cell, liver and skeletal muscle will be measured by LC/MS/MS.

Data analysis:
Ribavirin levels in blood and tissue will be compared in 3 groups at different time points.

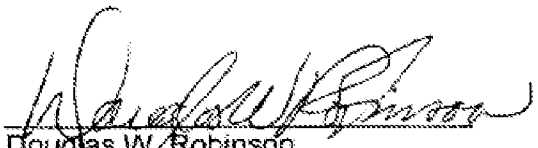
Time Plan: It is hoped that the testing can begin within the next month. Total testing is likely to take up to 3 months to complete. It will then be necessary to collect all data and prepare documentation to present the collected data as well as provide the necessary background material which will explain and support the

relevance of the results observed. This information will be submitted to the Examiner at the earliest possible time. It is contemplated that all work, including submission should be completed within the next 6 months.

Therefore a second six (6) month suspension is requested in order to permit the completion of the described testing and the preparation for submission of the data obtained from this testing.

Applicant therefore requests that prosecution be suspended for an additional period of six (6) months. The fee for this petition should be charged to the noted Deposit Account 50-332.

Respectfully Submitted,



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